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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,625	02/26/2002	W. Jerry Easterling	VULVODYNIA	1785

7590 12/12/2005

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,625	EASTERLING, W. JERRY	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (US 2002/0198136 A1), and further in view of Schor et al. (US 4369172).

Mak teaches or suggests the use of calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, felodipine, nicardipine, etc...) alone or in combination with variety compounds including NO donors, cholinergic modulators, phosphodiesterase inhibitors, superoxide scavengers, potassium channel activators, estrogen-like compounds, testosterone-like compounds, benzodiazepines, adrenergic nerve inhibitors, smooth muscle relaxants, adenosine receptor modulators, adenylyl cyclase activators, endothelin receptor antagonists,

bisphosphonates and cGMP-dependent protein kinase activators for the treatment of urogenital disorders including vulvodynia (abstract; page 1, para. 10; page 3, para. 15 ; page 4, para. 16, column column 7, para. 54; Examples 4-5, 15-16 and 19), wherein said calcium channel blockers can be administered in vaginal suppository from (page 3, para. 15 and page 3 para. 16).

Schlor is supplied as a reference to demonstrate the routine knowledge in preparing vaginal and rectal suppositories in various release time (i.e.., from 3 to 36 hours). See column 7, line 15 and column 8, lines 42-44. The reference lists calcium channel blocker such as dilitiazem as the suitable active ingredient of the claimed invention where said active ingredient can be prepared in various dosage form including vaginal suppository form (see column 6, line 42-43).

The teaching of Mak differs from the claimed invention in "administering said dosage from at least once daily until symptoms are reversed" and the specific dosage amount administered in "approximately 50mg".

One having ordinary skill in the art would have been motivated to make such modification to increase the efficacy and extend the usage of said calcium channel blocker containing composition by making the formulation in vaginal suppository to accommodate patient's preference and needs where the compliance could be improved with effective dosage form. Those of ordinary skill in the art will readily optimize effective dosages and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Regardless of the manner of administration, the specific dose may be calculated according to body weight, body surface area or organ size. Further refinement of the calculations necessary to determine the appropriate dosage for treatment involving each of the

above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 4-7 are properly rejected under 35 U.S.C. 103.

Response to Arguments

2. Applicant's arguments filed August 26, 2005 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that the prior art references (namely Mak and Schor patents) do not provide sufficient clarity and detail for the skilled artisan to arrive at the instantly claimed invention. Applicant asserts that the instantly claimed "once a day" is unobvious the cited "continuous delivery" since the more sustained the administration of any medication may result in the higher the risk of side effects.

This argument is not found persuasive. Unlike the applicant's assertion, throughout the specification, Mak teaches the administration of the compounds such as calcium channel blocker (i.e., diltiazem and nifedipine), in the form of "vaginal suppository, a cervical ring or an intrauterine device" (para. [0011]-[0025]), for the treatment of urogenital disorders including vulvodynia (abstract; para. [0010], [0015], [0016] and [0054]; Examples 4-5, 15-16 and 19). Although the delivery of calcium channel blocker, particularly diltiazem, in the form of intrauterine device (IUD) is exemplified in Example 4, the skilled artisan would have known that said calcium channel blocker (i.e., diltiazem) would be prepared and delivered in other dosage forms such as vaginal suppository taught in Mak. Thus, one having ordinary skill in the art would have been motivated to make such modification to increase the efficacy and extend the

usage of said calcium channel blocker containing composition by making the formulation in vaginal suppository to accommodate patient's preference and needs where the compliance could be improved with effective dosage form.

With respect to the instantly claimed "once a day" delivery of said calcium channel blocker, the skilled artisan at the time of the invention was made would have recognized by Schlor that vaginal suppository containing the active ingredient (i.e., diltiazem) could be prepared and delivered in various release time (i.e., from 3 to 36 hours). Furthermore, the skilled artisan at the time of the invention was made would have understood as taught by Mak that the administration of said calcium channel blocker (i.e., diltiazem) in "continuous delivery" which means "delivery of said compound in longer period of time by controlled or sustained delivery system or device" to the affected site would increase the efficacy of the pharmacological activity of the drug. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. No Claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

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